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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,855	11/13/2000	Brit Kalatz	RDID0006US	8566

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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,855

Applicant(s)

KALATZ ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10,33,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10,33,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. This is a Non-Final Office Action. The finality of the previous Office Action, mailed September 11, 2003, has been withdrawn due to the newly applied rejections summarized below.
2. The cancellation of claims 1-5, 11-32, 34, 35, and 38-45 has been acknowledged.
3. Claims 6-10, 33, 36, and 37 are examined on the merits.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-10, 33, 36, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Specific to claim 33, lines 23 and 25, the notations of C_i is recited in line 23 and CI in line 25 cause said claim to be vague and indefinite because it is unclear whether CI represent C_i or some other undefined variable in the equation. Clarification of the metes and bounds is required. Claims 6-10, 36, and 37 are rejected for being dependent from claim 33.
7. Claim 9 recites the limitation "the user" in line 1. There is insufficient antecedent basis for this limitation in the claim.

CLAIM REJECTIONS - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6-10, 33, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

9. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

10. The claimed invention, as recited in claims 6-10, 33, 36, and 37, is not enabled due to the instant specification does not provide any guidance for determining the values (variables) necessary for using the equation (8) for calculating G_p .

11. Specific to the variables G_a and D, the instant specification discloses that G_a as directed to the actual glucose concentration is determined by the empirical weight factor D, which is between 0.05 and 0.5 mmol/l/g (page 11, lines 1-5). The instant specification does not provide any guidance as how one of skill in the art to determine that the empirical weight factor D is either 0.05, 0.5 mmol/l/g, or any value within the specified range.

12. Further, G_a as directed to the actual glucose concentration is determined by the factor E wherein E is used in the equation $R_{kh} * F$ as E, whereby F is a factor close to 0.25 mmol/l/g (page 11, lines 17-19). The factor "E" is a non-enabled value due to R_{KH} not being enabled because it is not directly or indirectly defined in the specification as originally filed. Further, the instant specification does not provide any guidance as how one of skill in the art to select a value for F that is close to 0.25 mmol/l/g.

13. Specific to the variables X and E, the instant specification discloses X in the equation $G_{\text{basal}} = I_{\text{basal}} * SE * C$ is preferably used as X wherein C is between 0.05 to 0.5 mmol/l/g (page 11, lines 21-26). The factor "E" is a non-enabled value due to R_{KH} not being enabled because it is not directly or indirectly defined in the specification as originally filed. Further, the specification does not provide any guidance as how of skill in the art to determine that the empirical weight factor C is either 0.05, 0.5 mmol/l/g, or any value with the specified range.

14. Specific to the variable SE, the instant specification does provide any guidance as how SE is determined.

15. The lack of guidance for determining the values necessary for calculating G_p as directed to equation (8) does not enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as recited by claims 6-10, 33, 36, and 37.

16. Claims 6-10, 33, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being only enabling for "measuring" the actual glucose concentration, does not reasonably provide enablement for "determining" the actual glucose concentration using any other theoretical determination method. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

17. It is acknowledged that the instant specification is enabled for one of skill in the art to practice the claimed as directed to "measuring" the actual glucose concentration (pages 1-16). However, the instant specification does not reasonably provide enablement for determining the actual glucose concentration using any other theoretical determination method. Due to the lack of enabling disclosure for one of skill in the art to practice the claimed invention as directed to the determination of the actual glucose concentration using any other theoretical determination method, it would be unpredictable for one of skill in the art to practice the claimed invention commensurate in scope with these claims.

CONCLUSION

18. NO CLAIMS IS ALLOWED.

19. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.
22. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
12/19/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER